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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,580	10/06/2003	Glenn H. MacKal	380804.00116	6851
34802	7590	05/08/2007	EXAMINER	
HOLLAND & KNIGHT LLP			KEASEL, ERIC S	
ATTN: STEFAN V. STEIN/ IP DEPT.			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/681,580	MACKAL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Eric Keasel	3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5,6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5,6 and 9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on March 3, 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant has amended the claims so that the remaining claims do not read on the elected species (i.e. Figs. 2A-2C). Specifically, the claims now require the upper and lower surfaces to be transverse to an axis of the pill and at least one of the surfaces including multiple undulating configurations extending parallel to a plane of the surface. This is shown in unelected Figs. 4A-4C. Technically, this is non-responsive. However, to further prosecution, the examiner will withdraw the restriction requirement.

### ***Claim Objections***

2. Claim 1 is objected to because in claim 1, line 10, it appears that "said surface" should be --said at least one of said surfaces-- for consistency with "at least one of said surfaces" in line 8 that is being referred to in line 10 and to avoid confusion with the previous recitations to "an upper surface" and "a lower surface". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 recites that the undulating configurations are out of phase with each other. This is shown in Figs. 3A-3C (compare with Figs. 2A-2C). However, independent claim 1 now requires the upper and lower surfaces to be transverse to an axis of the pill and at least one of the surfaces including multiple undulating configurations extending parallel to a plane of the surface (which is shown in Figs. 4A-4C with the undulating configurations in phase with each other). So the originally filed application does not have support for the embodiment shown in Fig. 4A-4C in combination with the out-of-phase undulations. This is a new matter rejection.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3753

6. Claims 1-3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licher.

Licher discloses an automatic inflator comprising a body (see Fig. 3) for receiving a dissolvable annular pill (53, 163, 164, and other ref. nos. in other embodiments) including an upper surface and a lower surface with an undulating configuration in various embodiments (note also the serrations and apertures in various embodiments). Licher also discloses the peaks and troughs (claim 2), multiple surfaces with undulations (claim 3), undulations out of phase with each other (claim 5, see Fig. 11), the undulations extending radially (claim 6), and a center hole (claim 9). Licher no longer anticipates the claims, as the surfaces no longer have multiple undulating configurations extending parallel to the plane of the surface that is transverse to an axis of the pill.

Therefore, Licher does not disclose the exact shape of the pill as set forth in the amended claims. However, Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29-43). If one of ordinary skill in the art wants the pill to dissolve more quickly, they will choose a shape with greater surface area (i.e. more undulations) and if the artisan wants the pill to dissolve less quickly, they will choose a shape with a lesser surface area. Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

***Response to Arguments***

7. Applicant's arguments filed December 28, 2006 have been fully considered but they are not persuasive. Applicant argues that Licher only discloses undulations axially along the outside surface of the dissolvable pill. It should be noted that Licher also discloses the undulations along the top and bottom surface in Figs. 11 and 12 (but these are not transverse to the axis of the pill). More importantly, Licher gives a strong motivation to use other shapes based on desired time to dissolve the pill. Given the strong motivation to use other shapes (with an explicit reason to do so), one of ordinary skill in the art would be led to modify to Licher to get any of a number of shapes of the pill including the shapes set forth in the claims.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3753

9. Any inquiry concerning this communication should be directed to Eric Keasel at telephone number (571) 272-4929, who can normally be reached Monday-Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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